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<p>(21) International Application Number: <b>PCT/GB96/01473</b></p> <p>(22) International Filing Date: <b>20 June 1996 (20.06.96)</b></p> <p>(30) Priority Data:</p> <table border="0"> <tr> <td>9512888.0</td> <td>23 June 1995 (23.06.95)</td> <td>GB</td> </tr> <tr> <td>9512889.8</td> <td>23 June 1995 (23.06.95)</td> <td>GB</td> </tr> <tr> <td>9600352.0</td> <td>9 January 1996 (09.01.96)</td> <td>GB</td> </tr> <tr> <td>9600355.3</td> <td>9 January 1996 (09.01.96)</td> <td>GB</td> </tr> </table> <p>(71) Applicant (for all designated States except US): <b>GYRUS MEDICAL LIMITED [GB/GB]; Fountain Lane, St Mellons, Cardiff CF3 0LX (GB).</b></p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): <b>GOBLE, Nigel, Mark [GB/GB]; 6 Ty Newydd Drive, Castleton, Nr. Cardiff CF3 8SB (GB). GOBLE, Colin, Charles, Owen [GB/GB]; 5 Osbourne House, Clive Crescent, Penarth, South Glamorgan CF64 1AT (GB).</b></p> <p>(74) Agents: <b>BLATCHFORD, William, Michael et al.; Withers &amp; Rogers, 4 Dyer's Buildings, Holborn, London EC1N 2JT (GB).</b></p>		9512888.0	23 June 1995 (23.06.95)	GB	9512889.8	23 June 1995 (23.06.95)	GB	9600352.0	9 January 1996 (09.01.96)	GB	9600355.3	9 January 1996 (09.01.96)	GB	<p>(81) Designated States: <b>AL, AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</b></p> <p>Published With international search report.</p>
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<p>(54) Title: <b>AN ELECTROSURGICAL INSTRUMENT</b></p> <div data-bbox="406 1155 1266 1554"> </div> <p>(57) Abstract</p> <p>In an electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium (e.g. "underwater surgery") a bipolar electrode assembly has an active electrode having an exposed tissue treatment portion (34A), a return electrode (38) having an exposed fluid contact surface, and an insulating member (36) positioned between and electrically insulating the active electrode in the return electrode. The insulating member serves to space apart the exposed active electrode treatment portion and the exposed fluid contact portion of the return electrode. The dimensions and configurations of the exposed portions of the electrodes and of the insulating member are such that when the electrode assembly is immersed in a conductive fluid medium, the ratio between the longest and shortest conduction path lengths between the active and return (b/a) electrodes is less than or equal to 2:1. The invention also includes a combination of an electrosurgical instrument and a radio frequency generator.</p>														

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AN ELECTROSURGICAL INSTRUMENT

This invention relates to an electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, and to an electrosurgical system apparatus including such an instrument.

Endoscopic electrosurgery is useful for treating tissue in cavities of the body, and is normally performed in the presence of a distension medium. When the distension medium is a liquid, this is commonly referred to as underwater electrosurgery, this term denoting electrosurgery in which living tissue is treated using an electrosurgical instrument with a treatment electrode or electrodes immersed in liquid at the operation site. A gaseous medium is commonly employed when endoscopic surgery is performed in a distensible body cavity of larger potential volume in which a liquid medium would be unsuitable, as is often the case in laparoscopic or gastroenterological surgery.

Underwater surgery is commonly performed using endoscopic techniques, in which the endoscope itself may provide a conduit (commonly referred to as a working channel) for the passage of an electrode. Alternatively, the endoscope may be specifically adapted (as in a resectoscope) to include means for mounting an electrode, or the electrode may be introduced into a body cavity via a separate access means at an angle with respect to the endoscope - a technique commonly referred to as triangulation. These variations in technique can be subdivided by surgical speciality, where one or other of the techniques has particular advantages given the access route to the specific body cavity. Endoscopes with integral working channels, or those characterised as resectoscopes, are generally employed when the body cavity may be accessed through a natural body opening - such as the cervical canal to access the endometrial cavity of the uterus, or the urethra to access the prostate gland and the bladder. Endoscopes specifically designed for use in the endometrial cavity are referred to as hysteroscopes, and those designed for use in the urinary tract include cystoscopes, urethrosopes and resectoscopes. The procedures of transurethral resection or vaporisation of the prostate gland are known as TURP and EVAP respectively. When there is no natural body opening through which an endoscope may

be passed, the technique of triangulation is commonly employed. Triangulation is commonly used during underwater endoscopic surgery on joint cavities such as the knee and the shoulder. The endoscope used in these procedures is commonly referred to as an arthroscope.

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Electrosurgery is usually carried out using either a monopolar instrument or a bipolar instrument. With monopolar electrosurgery, an active electrode is used in the operating region, and a conductive return plate is secured to the patient's skin. With this arrangement, current passes from the active electrode through the patient's tissues to the external return plate. Since the patient represents a significant portion of the circuit, input power levels have to be high (typically 150 to 250 watts), to compensate for the resistive current limiting of the patient's tissues and, in the case of underwater electrosurgery, power losses due to the fluid medium which is rendered partially conductive by the presence of blood or other body fluids. Using high power with a monopolar arrangement is also hazardous, due to the tissue heating that occurs at the return plate, which can cause severe skin burns. There is also the risk of capacitive coupling between the instrument and patient tissues at the entry point into the body cavity.

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With bipolar electrosurgery, a pair of electrodes (an active electrode and a return electrode) are used together at the tissue application site. This arrangement has advantages from the safety standpoint, due to the relative proximity of the two electrodes so that radio frequency currents are limited to the region between the electrodes. However, the depth of effect is directly related to the distance between the two electrodes; and, in applications requiring very small electrodes, the inter-electrode spacing becomes very small, thereby limiting tissue effect and the output power. Spacing the electrodes further apart would often obscure vision of the application site, and would require a modification in surgical technique to ensure direct contact of both electrodes with the tissue.

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There are a number of variations to the basic design of the bipolar probe. For example, U.S. Patent Specification No. 4706667 describes one of the fundamentals of the design,

namely that the ratio of the contact areas of the return electrode and of the active electrode is greater than 7:1 and smaller than 20:1 for cutting purposes. This range relates only to cutting electrode configurations. When a bipolar instrument is used for desiccation or coagulation, the ratio of the contact areas of the two electrodes may be reduced to approximately 1:1 to avoid differential electrical stresses occurring at the contact between the tissue and the electrode.

The electrical junction between the return electrode and tissue can be supported by wetting of the tissue by a conductive solution such as normal saline. This ensures that the surgical effect is limited to the needle or active electrode, with the electric circuit between the two electrodes being completed by the tissue. One of the obvious limitations with the design is that the needle must be completely buried in the tissue to enable the return electrode to complete the circuit. Another problem is one of the orientation: even a relatively small change in application angle from the ideal perpendicular contact with respect to the tissue surface, will change the contact area ratio, so that a surgical effect can occur in the tissue in contact with the return electrode.

Cavity distension provides space for gaining access to the operation site, to improve visualisation, and to allow for manipulation of instruments. In low volume body cavities, particularly where it is desirable to distend the cavity under higher pressure, liquid rather than gas is more commonly used due to better optical characteristics, and because it washes blood away from the operative site.

Conventional underwater electrosurgery has been performed using a non-conductive liquid (such as 1.5% glycine) as an irrigant, or as a distension medium to eliminate electrical conduction losses. Glycine is used in isotonic concentrations to prevent osmotic changes in the blood when intra-vascular absorption occurs. In the course of an operation, veins may be severed, with resultant infusion of the liquid into the circulation, which could cause, among other things, a dilution of serum sodium which can lead to a condition known as water intoxication.

5 The applicants have found that it is possible to use a conductive liquid medium, such as normal saline, in underwater endoscopic electrosurgery in place of non-conductive, electrolyte-free solutions. Normal saline is the preferred distension medium in underwater endoscopic surgery when electrosurgery is not contemplated, or a non-electrical tissue effect such as laser treatment is being used. Although normal saline (0.9%w/v; 150mmol/l) has an electrical conductivity somewhat greater than that of most body tissue, it has the advantage that displacement by absorption or extravasation from the operative site produces little physiological effect, and the so-called water intoxication effects of non-conductive, electrolyte-free solutions are avoided.

10 The applicants have developed a bipolar instrument suitable for underwater electrosurgery using a conductive liquid medium. A first aspect of the invention is as defined in claim 1 accompanying this description. Other aspects of the invention are as defined in claim 7, which relates to an electrosurgical system including an instrument and a generator, 15 claims 12, 19 and 23 each directed to an electrosurgical instrument, and claims 31 and 37 directed to methods of desiccating and vaporising tissue. Some of the preferred features of the different aspects of the invention are set out in the dependent claims.

20 The electrode structure of this instrument, in combination with an electrically-conductive fluid medium largely avoids the problems experienced with monopolar or bipolar electrosurgery. In particular, input power levels are much lower than those generally necessary with a monopolar arrangement (typically 100 watts). Moreover, because of the relatively large spacing between its electrodes, an improved depth of effect is obtained compared with conventional bipolar arrangements.

25 The invention will now be described by way of example with reference to the drawings in which:

30 Figure 1 is a diagram showing an electrosurgical system in accordance with the invention;

Figure 2 is a side view of a portion of an electrosurgical instrument forming part of the system of Figure 1;

Figure 3 is a cross-section of part of an alternative electrosurgical instrument in accordance with the invention, the instrument being sectioned along a longitudinal axis;

Figure 4 is a graph illustrating the hysteresis of the electrical load impedance and dissipated radio frequency power which occurs between use of an instrument in accordance with the invention in desiccating and vaporising modes;

Figure 5 is a block diagram of the generator of the electrosurgical system shown in Figure 1;

Figure 6 is a diagrammatic side view of the instrument of Figure 3 showing the use of the instrument for tissue removal by vaporisation;

Figure 7 is a diagrammatic side view of an instrument similar to that shown in Figure 6, showing the use of the instrument for tissue desiccation or coagulation; and

Figures 8, 9 and 10 are side views of further electrosurgical instruments in accordance with the invention, showing different electrode and insulator configurations.

Referring to the drawings, Figure 1 shows electrosurgical apparatus including an electrosurgical generator 10 having an output socket 10S providing a radio frequency (RF) output for a bipolar instrument, in the form of a handpiece 2 and a detachable electrode unit 28, via a connection cord 14. Activation of the generator 10 may be performed from the handpiece 12 via a control connection in the cord 14, or by means of a footswitch unit 16, as shown, connected separately to the rear of the generator 10 by a footswitch connection cord 18. In the illustrated embodiment, the footswitch unit 16 has two footswitches 16A and 16B for selecting a desiccation mode and a vaporisation mode of the generator 10 respectively. The generator front panel has push buttons 20 and 22 for

respectively setting desiccation and vaporisation power levels, which are indicated in a display 24. Push buttons 26 are provided as an alternative means for selection between the desiccation and vaporisation modes.

5 The instrument need not include a handpiece, but may simply include a connector for mounting to another device such as a resectoscope. In Figure 1 the instrument has an electrode unit 28 which is shown mounted to the handpiece 12.

10 The electrode unit E may take a number of different forms, some of which are described below.

15 In a basic configuration, shown in Figure 2, an electrode unit for detachable fastening to an instrument handpiece comprises a shaft 30 which may be a conductive tube covered with an insulating sheath 30S, with an electrode assembly 32 at a distal end of the shaft 30. At the other end of the shaft (not shown) means are provided for connecting the unit to a handpiece both mechanically and electrically.

20 The electrode assembly 32 comprises a central active electrode 34 which is exposed at the extreme distal end of the unit to form a treatment portion of the electrode. Preferably the active electrode is a metallic wire which extends as a central conductor through the whole of the shaft 30 to a contact at the proximal end (not shown in the drawing). Surrounding the electrode 34 and the inner conductor is an insulating sleeve 36 the distal end of which is exposed proximally of the exposed treatment portion of the electrode 34. Typically, this sleeve is made of a ceramic material to resist damage from arcing. Surrounding the sleeve 25 36 is the return electrode 38 in the form of a metallic tube which is electrically (and optionally also mechanically) integral with the metallic tubular body of the shaft 30. This return electrode terminates at a point short of the end of the sleeve 36 so that it is set back from the exposed treatment portion of the active electrode 34 and is both radially and axially spaced from the latter. It will be appreciated that, principally due to the much 30 larger diameter of the return electrode in comparison to that of the tissue contact electrode, the return electrode provides an exposed fluid contact surface which has a surface area



very much greater than that of the exposed active electrode treatment portion. The insulating sheath 30S terminates at a location proximally spaced from the distal end of the return electrode 38 in order to provide the required surface area for the return electrode fluid contact surface. At the distal end of the electrode unit, the diameter of the return conductor is typically in the region of from 1mm to 5mm. The longitudinal extent of the exposed part fluid contact surface the return electrode 38 is typically between 1mm and 5mm with the longitudinal spacing from the return electrode 38 to the exposed active electrode treatment portion between 1mm and 5mm. Further aspects of the configuration and dimensioning of electrode assemblies are set out in more detail below.

In effect, the electrode structure shown in Figure 2 is bipolar, with only one of the electrodes (34) actually extending to the distal end of the unit. This means that, in normal use when the electrode assembly is immersed in a conductive fluid medium, the return electrode 38 remains spaced from the tissue being treated and a current path exists between the two electrodes via the tissue and the conductive fluid medium which is in contact with the return electrode.

The axial spacing of the electrodes permits a very fine electrode structure in terms of diameter since the insulation path is considerably longer than a bipolar electrode having merely radial spacing between exposed electrode surfaces. This allows higher powers to be used than with conventional electrode structures without causing unwanted arcing, or in the case of electrosurgical cutting or vaporisation treatment, without causing electrode unit damage due to excessive arcing at high temperatures.

The particular staggered arrangement shown affords the surgeon a view of the tissue contact electrode tip, and permits a large range of applied angles with respect to the tissue surface, which is particularly important in the confined spaces typical of endoscopic surgery.

Referring to Figure 3, an alternative electrode unit for detachable fastening to the electrosurgical instrument handpiece 12 shown in Figure 1 comprises a shaft 30, which

is constituted by a semi-flexible tube made of stainless steel or phynox electroplated in copper or gold, with an electrode assembly 32 at a distal end thereof. At the other end (not shown) of the shaft 30, means are provided for connecting the electrode unit to the handpiece both mechanically and electrically.

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The electrode assembly 32 includes a central, active or tissue contact electrode 34 which is made of platinum, platinum/iridium or platinum/tungsten, and is constituted by a generally hemispherical exposed tip 34A and an integral central conductor 34B. The conductor 34B is electrically connected to a central copper conductor 34C by fastening a thin stainless steel spring 34D over the adjacent end portions of the conductors 34B and 34C, thereby providing an electrical connection between the handpiece of the instrument and the exposed tip 34A. A ceramic insulation sleeve 36 surrounds the conductor 34B, the spring 34D and the adjacent end portion of the copper conductor 34C. The sleeve 36 has an exposed portion 36A which surrounds the distal end portion of the conductor 34B. A return electrode 38, which forms a distal end portion of the shaft 30 providing a cylindrical fluid contact surface, closely surrounds the sleeve 36 and extends over the copper conductor 34C spaced from the latter by an insulation sleeve 40. An outer insulating heat shrink or polyimide coating 30S surrounds the shaft 30 and proximal portion of the return electrode 38.

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When used in combination with an electrosurgical generator as shown in Figure 1, the electrode unit of Figure 3 can be employed in a conductive fluid medium for tissue removal by vaporisation, for sculpturing and contouring menisci during arthroscopic surgery, or for desiccation, depending on the manner in which the generator is controlled. Figure 4 illustrates how the generator can be controlled to take advantage of the hysteresis which exists between the desiccation and the vaporising modes of the electrode unit. Thus, assuming the electrode assembly 32 of the unit is immersed in a conductive medium such as saline, there is an initial load impedance "r" at point "O", the magnitude of which is defined by the geometry of the electrode assembly and the electrical conductivity of the fluid medium. The value of "r" changes when the active electrode 34 contacts tissue, the higher the value of "r" the greater is the propensity of the electrode assembly 32 to enter

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the vaporisation mode. When RF power is applied to the electrode assembly 32 the fluid medium heats up. Assuming the fluid medium is normal saline (0.9% w/v), the temperature coefficient of conductivity of the fluid medium is positive, so that the corresponding impedance coefficient is negative. Thus, as power is applied, the impedance initially falls and continues to fall with increasing dissipation power to point "B", at which point the saline in intimate contact with the electrode assembly 32 reaches its boiling point. Small vapour bubbles form on the surface of the active tip 34A and the impedance then starts to rise. After point "B", as power dissipation is increased further, the positive power coefficient of impedance is dominant, so that increasing power now brings about increasing impedance.

As a vapour pocket forms from the vapour bubbles, there is an increase in the power density at the residual electrode/saline interface. There is, however, an exposed area of the active electrode tip 34A not covered by vapour bubbles, and this further stresses the interface, producing more vapour bubbles and thus even higher power density. This is a run-away condition, with an equilibrium point only occurring once the electrode is completely enveloped in vapour. For given set of variables, there is a power threshold before this new equilibrium can be reached (point "C").

The region of the graph between the points "B" and "C", therefore, represents the upper limit of the desiccation mode. Once in the vaporisation equilibrium state, the impedance rapidly increases to around 1000 ohms, with the absolute value depending on the system variables. The vapour pocket is then sustained by discharges across the vapour pocket between the active electrode tip 34A and the vapour/saline interface. The majority of power dissipation occurs within this pocket, with consequent heating of the tip 34A. The amount of energy dissipation, and the size of the pocket, depends on the output voltage. If this is too low, the pocket will not be sustained, and if it is too high the electrode assembly 32 will be destroyed. Thus, in order to prevent destruction of the electrode assembly 32, the power output of the generator must be reduced once the impedance has reached the point "D". It should be noted that, if the power is not reduced at this point, the power/impedance curve will continue to climb and electrode destruction would occur.

The dotted line E indicates the power level above which electrode destruction is inevitable. As the power is reduced, the impedance falls until, at point "A", the vapour pocket collapses and the electrode assembly 32 reverts to the desiccation mode. At this point, power dissipation within the vapour pocket is insufficient to sustain it, so that direct contact between the active electrode tip 34A and the saline is re-established, and the impedance falls dramatically. The power density at the tip 34A also falls, so that the temperature of the saline falls below boiling point. The electrode assembly 32 is then in a stable desiccation mode.

Generator power control to achieve the required desiccation, tissue cutting and vaporisation functions is carried out by sensing the peak RF voltage appearing across the output connections of the generator and by rapidly reducing the delivered output power whenever a preselected peak voltage threshold is reached. In a desiccation mode at least, this power reduction is significantly more than that required merely to bring the peak output voltage below the threshold. Preferably the power reduction is at least 50% to take advantage of the hysteresis characteristic described above with reference to Figure 4.

Referring to Figure 5, the generator comprises a radio frequency (RF) power oscillator 60 having a pair of output connections 60C for coupling via output terminals 62 to the load impedance 64 represented by the electrode assembly when in use. Power is supplied to the oscillator 60 by a switched mode power supply 66.

In the preferred embodiment, the RF oscillator 60 operates at about 400 kHz, with any frequency from 300 kHz upwards into the HF range being feasible. The switched mode power supply typically operates at a frequency in the range of from 25 to 50 kHz. Coupled across the output connections 60C is a voltage threshold detector 68 having a first output 18A coupled to the switched mode power supply 16 and a second output 18B coupled to an "on" time control circuit 70. A microprocessor controller 72 coupled to the operator controls and display (shown in Figure 1), is connected to a control input 66A of the power supply 66 for adjusting the generator output power by supply voltage variation

and to a threshold-set input 68C of the voltage threshold detector 68 for setting peak RF output voltage limits.

5 In operation, the microprocessor controller 72 causes power to be applied to the switched mode power supply 66 when electrosurgical power is demanded by the surgeon operating an activation switch arrangement which may be provided on a handpiece or footswitch (see Figure 1). A constant output voltage threshold is set independently of the supply voltage via input 68C according to control settings on the front panel of the generator (see Figure 1). Typically, for desiccation or coagulation the threshold is set at a desiccation  
10 threshold value between 150 volts and 200 volts. When a cutting or vaporisation output is required, the threshold is set to a value in the range of from 250 or 300 volts to 600 volts. These voltage values are peak values. Their being peak values means that for desiccation at least it is preferable to have an output RF waveform of low crest factor to give maximum power before the voltage is clamped at the values given. Typically a crest  
15 factor of 1.5 or less is achieved.

When the generator is first activated, the status of the control input 60I of the RF oscillator 60 (which is connected to the "on" time control circuit 70) is "on", such that the power switching device which forms the oscillating element of the oscillator 60 is switched on  
20 for a maximum conduction period during each oscillation cycle. The power delivered to the load 64 depends partly on the supply voltage applied to the RF oscillator 60 from the switched mode power supply 66 and partly on the load impedance 64. If the supply voltage is sufficiently high, the temperature of the liquid medium surrounding the electrodes of the electrosurgical instrument (or within a gaseous medium, the temperature of liquids contained within the tissue) may rise to such an extent that the liquid medium  
25 vaporises, leading to a rapid increase in load impedance and a consequent rapid increase in the applied output voltage across terminals 12. This is an undesirable state of affairs if a desiccation output is required. For this reason, the voltage threshold for a desiccation output is set to cause trigger signals to be sent to the "on" time control circuit 70 and to the switched mode power supply 66 when the threshold is reached. The "on" time control  
30 circuit 70 has the effect of virtually instantaneously reducing the "on" time of the RF

oscillator switching device. Simultaneously, the switched mode power supply is disabled so that the voltage supplied to oscillator 60 begins to fall.

5 The output voltage of the generator is important to the mode of operation. In fact, the output modes are defined purely by output voltage, specifically the peak output voltage. The absolute measure of output voltage is only necessary for multiple term control. However, a simple single term control (i.e. using one control variable) can be used in this generator in order to confine the output voltage to predetermined limit voltages. Thus, the voltage threshold detector 68 shown in Figure 5 compares the RF peak output voltage with  
10 a preset DC threshold level, and has a sufficiently fast response time to produce a reset pulse for the "on" time control circuit 70 within one RF half cycle.

15 Maximum absorbed power coincides with the electrode condition existing immediately before formation of vapour bubbles, since this coincides with maximum power distribution and the greatest wetted electrode area. It is therefore desirable that the electrode remains in its wetted state for the maximum desiccation power. Use of voltage limit detection brings about a power reduction which allows the vapour bubbles to collapse which in turn increases the ability of the active electrode to absorb power. It is  
20 for this reason, that the generator includes a control loop having a large overshoot, in that the feedback stimulus of the peak voltage reaching the predefined threshold causes a large instantaneous reduction in power by causing a reduction in peak output voltage to a level significantly below the peak output voltage level set by the threshold detector 68. This control overshoot ensures a return to the required wetted state.

25 Further details of the generator and its operation are described in our copending British Patent Application No. 9604770.9, the contents of which are incorporated in this specification by reference.

30 In the light of the above, it will be apparent that the electrode unit of Figure 3 can be used for desiccation by operating the unit in the region of the graph between the point "O" and a point in the region between the points "B" and "C". In this case, the electrode assembly

32 is introduced into a selected operation site with the active tip 34A adjacent to the tissue to be treated, and with the tissue and the active tip and the return electrode immersed in the saline. The generator is then activated (and cyclically controlled as described above) to supply sufficient power to the electrode assembly 32 to maintain the saline adjacent to the active tip 34A at, or just below, its boiling point without creating a vapour pocket surrounding the active tip. The electrode assembly is manipulated to cause heating and desiccation of the tissue in a required region adjacent to the active tip 34A. The electrode unit can be used for vaporisation in the region of the graph between the point "D" and the dotted line F which constitutes the level below which vaporisation is no longer stable. The upper part of this curve is used for tissue removal by vaporisation. In this mode, a light application of the instrument to the tissue to be treated enables sculpturing and contouring to be carried out.

The electrode assembly 32 preferably has unitary electrodes with a return: active electrode surface area ratio in the range of from 5:1 to 40:1 (that is to say the ratio of the surface areas of the exposed portions of the two electrodes are in this range).

Figure 6 illustrates the use of the electrode unit of Figure 3 for tissue removal by vaporisation, the electrode unit being immersed in conductive fluid 78. Thus, the electrode unit creates a sufficiently high energy density at the active tip 34A to vaporise tissue 80, and to create a vapour pocket 82 surrounding the active tip. The formation of the vapour pocket 82 creates about a 10-fold increase in contact impedance, with a consequent increase in output voltage. Arcs 84 are created in the vapour pocket 82 to complete the circuit to the return electrode 38. Tissue 80 which contacts the vapour pocket 82 will represent a path of least electrical resistance to complete the circuit. The closer the tissue 80 comes to the active tip 34A, the more energy is concentrated to the tissue, to the extent that the cells explode as they are struck by the arcs 84, because the return path through the connective fluid (saline in this case) is blocked by the high impedance barrier of the vapour pocket 82. The saline solution also acts to dissolve or disperse the solid products of vaporisation.

In use, the electrode assembly 32 is introduced into a selected operation site with the active electrode tip 34A adjacent the tissue to be vaporised, and with the tissue, the active tip and the return electrode 38 immersed in the saline 78. The RF generator is activated to supply sufficient power (as described above with reference to Fig. 4) to the electrode assembly 32 to vaporise the saline and to maintain a vapour pocket surrounding the tissue contact electrode. When the electrode unit is used for sculpturing or contouring menisci during arthroscopic surgery, the electrode assembly 32 is applied with light pressure at the selected operation site, and is manipulated so that the part-spherical surface of the active tip 34A moves across the surface to be treated, smoothing away tissue, and in particular menisci, with a sculpturing or contouring action.

Figure 7 illustrates the use of an electrode unit similar to that of Figure 3 used for tissue desiccation. In the desiccation mode, output power is delivered to the electrodes in a first output range, so that current flows from the active electrode 34 to the return electrode 38. As described above, the output power causes the saline solution adjacent to the active electrode 34 to become heated, preferably to a point at or near the boiling point of the saline solution. This creates small vapour bubbles on the surface of the active electrode 14 that increase the impedance about the active electrode 34.

The body tissue 80 typically has lower impedance than the impedance of the combination of vapour bubbles and saline solution adjacent to the active electrode 34. When an active electrode 34 surrounded by small vapour bubbles and saline solution is brought into contact with tissue 80, the tissue 80 becomes part of the preferred electrical current path. Accordingly, the preferred current path goes out of the active electrode 34 at the point of tissue contact, through the tissue 80, and then back to the return electrode 38 via the saline solution, as shown in Figure 7.

The invention has particular application in desiccating tissue. For tissue desiccation, one preferred approach is to contact only part of the active electrode to the tissue, with the remainder of the active electrode remaining remote from the tissue and surrounded by saline solution so that current can pass from the active to return electrode, via the saline



solution, without passing through the tissue. For example, in the embodiment shown in Figure 7, only the distal portion of the active electrode contacts the tissue, with the proximal portion remaining spaced away from the tissue.

5 The invention can achieve desiccation with no or minimal charring of the tissue. When the active electrode 34 contacts the tissue 80, current passes through the tissue, causing the tissue at and around the contact point to desiccate. The area and volume of desiccated tissue expands generally radially outward from the point of contact.

10 In the embodiment shown in Figure 7, the exposed treatment portion of the active electrode 34 is longer than it is wide. This allows the electrode tip to contact the tissue surface while still maintaining most of the exposed treatment portion out of contact with the tissue even when the instrument is angled with respect to the tissue surface. Because most of the exposed portion of the electrode is out of contact with the tissue, the current  
15 path will more easily shift, upon desiccation of a sufficient tissue volume, from the path through the tissue to a path that goes directly from the active electrode to the saline solution.

20 In the electrode unit shown in Figure 3 the exposed portion of the active electrode 34 is relatively short compared with the length of the insulation member 36 between the active electrode 34 and the return electrode 38. With such an electrode configuration, bistable operation of the instrument inherent in the hysteresis characteristic described above with reference to Figure 4 applies, in that the instrument can be used in a desiccation mode or in a low power vaporisation mode. In some circumstances, particularly if the exposed  
25 treatment portion of the active electrode is long, bistable operation may be difficult to achieve.

30 Measures to overcome this difficulty will now be described with reference to Figure 8 which shows an electrode unit comprising a shaft 30 constituted by a semi-flexible tube made of stainless steel or phynox electroplated in copper or gold, with an electrode assembly 32 at a distal end thereof. The electrode assembly 32 includes a central active

electrode 34 having an elongate exposed treatment portion 34A (which may be referred to as a "needle" electrode), and an integral central conductor 34B. A cylindrical ceramic insulation sleeve 36 surrounds the conductor 34B, and a return electrode 38, which is constituted by the distal end portion of the shaft 30, abuts a proximal end of the sleeve 36.

5 An outer insulating polyimide coating 40 surrounds the proximal portion of the shaft adjacent the return electrode 38, thereby providing the return electrode with an annular fluid contact surface extending from the edge of the coating 40 to the insulation sleeve 36. The insulation sleeve 36 has a distal end face 36A of a diameter such that the step radius (i.e. the distance between the circumferential edge of the end face 36A and the outside

10 diameter of the active electrode 34) is at least 1/20th of the length of the exposed active electrode treatment portion 34a. The insulation sleeve 36 thus has a shoulder (or step) which is coaxial with the active electrode 34. In use, this step prevents local arcing which could otherwise occur at the proximal end of the exposed active electrode treatment portion 34A, rendering the distal end of the treatment portion 34A ineffective.

15 To consider the operation of the electrode in more detail, when the electrode unit is operated in a tissue cutting or vaporising mode, a vapour bubble is formed around the active electrode treatment portion 34A. This bubble is sustained by arcing within it. The greater the applied voltage, the greater is the size of the bubble. The energy dissipated by

20 each arc is impedance-limited by the remaining fluid in the conduction path and by the source impedance of the generator. However, an arc behaves as a negative impedance in that if the energy in the arc is sufficiently high, an ionised path of very low impedance is formed. This can lead to an unstable condition of ever-decreasing ionised path impedance unless the impedance of the fluid between the bubble and the return electrode is sufficient

25 to act as a limit on dissipated power. It is also possible for the vapour pocket around the active electrode treatment portion to encroach the return electrode. In these circumstances, the arc energy is limited only by generator source impedance, but such power limitation is poor and cannot be adjusted according to electrode size. For these reasons, the dimensions and configuration of the insulation sleeve 36 should be such as

30 to define a minimum conduction path length of 1mm between the active electrode treatment portion 34A and the fluid contact surface of the return electrode 38. This

minimum path length is, in the case of the embodiment shown in Figure 8, the length  $a$  of the sleeve 36 plus the step radius  $c$ , as shown in Figure 8.

5 A further consideration is the possibility of a vapour pocket forming only over part of the exposed treatment portion 34A of the active electrode 34. When the applied voltage and power are sufficiently high, a vapour pocket will form around the active electrode exposed treatment portion. Preferably, the pocket is formed uniformly over the entire length of the treatment portion. In such a situation, the load impedance presented to the generator can change by as much as a factor of 20. However, when there are significant differences in  
10 the conduction path length between the return electrode fluid contact surface and different parts of the exposed active electrode treatment portion 34A, a voltage gradient is established over the length of each electrode. Preferably, the fluid contact surface is large enough and has an aspect ratio such that its length is at least as great as its diameter so as to minimise a voltage gradient over its surface. Nevertheless, with some insulation sleeve and active electrode configurations, the voltage gradient can be sufficiently large to enable  
15 vapour pocket formation only over that part of the exposed treatment portion closest to the fluid contact surface, leaving the extreme distal end of the exposed treatment portion still in contact with the conductive fluid. Thus, the voltage gradient is established within the conductive fluid where the edge of the vapour pocket intersects the surface of the active electrode treatment portion 34A. The electrical behaviour of such a partially enveloped active electrode treatment portion is very different from that of a fully enveloped treatment portion. The impedance transition from the wetted state to the vapour enveloped state is far less marked than described above with reference to Figure 4. In terms of controlling generator output by sensing peak voltage, the behaviour of the  
20 electrode assembly is no longer bistable. However, the power demand is considerably higher as a result of the vaporisation voltage presented across the low impedance wetted region of the active electrode treatment portion. The clinical effect is not only the required vaporisation, but also an undesirable thermal damaging effect resulting from the increased power dissipation.

Partial enveloping of the active electrode treatment portion can be largely avoided by ensuring that the ratio of the length of the conductive path between the furthestmost point of the active electrode treatment portion and the length of the shortest conductive path between the active electrode treatment portion and the fluid contact surface is less than or equal to 2 : 1, i.e.  $b/(a+c) \leq 2$ .

In some circumstances, it may be found that the conductive path length between the active and return electrodes is too long to allow vaporisation of the conductive fluid due to the consequent large series impedance represented by the fluid. Too large a voltage drop may result in a preset voltage threshold being reached before vaporisation can be achieved. Preferably, then, the ratio of the greatest conduction path length to the annular peripheral length of the return electrode fluid contact surface is no more than 1.43 : 1. In the case of a cylindrical fluid contact surface which is coaxial with the active electrode, the ratio of the greatest conduction path length to the fluid contact surface diameter is less than or equal to 4.5 : 1. Thus, with reference to Figure 8,  $b/d \leq 4.5$ .

The primary use of the electrode unit shown in Figure 8 is for cutting tissue, with at least part of the active electrode treatment portion 34A buried in the tissue to be treated and with the generator operated in the vaporisation portion of the impedance/power characteristics shown in Figure 4.

Alternative active electrode configurations include forming the exposed treatment portion 34A as a hook, as shown in Figure 9. In this case, the insulation sleeve is conical, tapering from the fluid contact surface of the return electrode 38 to the distal end face 36A.

A further alternative, shown in Figure 10 has an active electrode treatment portion 34a in the shape of a looped hook.

In the embodiments of Figures 8, 9 and 10, it will be seen that the dimensions  $a$ ,  $b$ ,  $c$ ,  $d$  are such as to fall within the ratio limits described above. Furthermore, in each case, the electrode assembly may be viewed as having a treatment axis 42, being the axis along

which the instrument may be introduced towards the tissue, the return electrode 38 being set back in the direction of the treatment axis from the active electrode 34A. For the purpose of comparing the different conduction path lengths between the return electrode and different parts of the active electrode treatment portion, paths in a common plane should be considered, the plane containing the treatment axis 42. In the case of the views of Figures 8, 9 and 10, the illustrated path lengths are, of course, in the plane of the paper bearing the views.

CLAIMS

1. An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, comprising an instrument shaft and an electrode assembly at a distal end of the shaft, wherein the electrode assembly comprises:
  - a single active electrode having an exposed tissue treatment portion,
  - a return electrode having an exposed fluid contact surface, and
  - an insulating member positioned between and electrically insulating the active electrode and the return electrode and serving to space apart the exposed treatment portion of the active electrode and the exposed fluid contact portion of the return electrode,and wherein the dimensions and configuration of the exposed treatment portion, the exposed fluid contact portion and the insulation member are such that when the electrode assembly is immersed in a conductive fluid medium the ratio of (i) the length of the shortest conduction path ( $P_1$ ) through the fluid medium between the exposed fluid contact surface and that part of the exposed treatment portion which is furthest from the exposed fluid contact surface, to (ii) the length of the shortest conduction path ( $P_2$ ) through the fluid medium between the exposed fluid contact surface and the exposed treatment portion, is less than or equal to 2 to 1.
2. An instrument according to claim 1, wherein the exposed treatment portion of the active electrode projects in a first direction from the insulation member, the fluid contact surface of the return electrode is set back from the active electrode treatment portion, and the insulating member surrounds the active electrode and, between the active electrode exposed portion and the return electrode fluid contact surface, projects outwardly in a second direction perpendicular to the first direction to define an insulation barrier to divert electrical current flow through the fluid medium thereby to increase said shortest conduction path length ( $P_2$ ) between the exposed fluid contact surface and the exposed treatment portion.

3. An instrument according to claim 1, wherein the first direction defines a treatment axis and said two shortest conduction paths ( $P_1$ ,  $P_2$ ) lie in a common plane containing the treatment axis.
- 5 4. An instrument according to claim 1, wherein the length of said shortest conduction path ( $P_2$ ) through the fluid medium between the exposed fluid contact surface and the exposed treatment portion is at least 1mm.
- 10 5. An instrument according to claim 1, wherein the exposed fluid contact surface is generally cylindrical and has a length and a diameter, the length of the fluid contact surface being at least as great as its diameter and wherein the ratio of (i) the shortest conduction path ( $P_1$ ) through the fluid medium between the fluid contact surface and that part of the exposed treatment portion which is furthest from the fluid contact surface, to (ii) the fluid contact surface diameter, is at most  
15 4.5 to 1.
- 20 6. An instrument according to claim 1, wherein the ratio of (i) the length of the shortest conduction path ( $P_1$ ) through the fluid medium between the exposed fluid contact surface and that part of the exposed treatment portion which is furthest from the exposed fluid contact surface, to (ii) the length of the shortest conduction path ( $P_2$ ) through the fluid medium between the exposed fluid contact surface and the exposed treatment portion, is greater than or equal to 1.25.
- 25 7. An electrosurgical system according to claim 1, further comprising an electrosurgical generator for supplying radio frequency power to the instrument, the generator including an output stage having at least a pair of electrosurgical output connections connectible respectively to the active electrode and the return electrode of the instrument, a sensing circuit for deriving a sensing signal representative of the peak radio frequency output voltage developed between the  
30 output connections, and a power adjustment circuit for automatically causing a

reduction in delivered output power when the sensing signal is indicative of a predetermined peak radio frequency output voltage having been reached.

- 5 8. A system according to claim 7, wherein the power adjustment circuit is operable to cause at least a 50% reduction in delivered output power when the sensing signal is indicative of said threshold having been reached, said reduction being effected with a period of 100 $\mu$ s or less.
- 10 9. A system according to claim 8, wherein the power adjustment circuit is operable to effect said reduction in a period of 20 $\mu$ s or less.
- 15 10. A system according to claim 7, wherein the output stage includes at least one radio frequency power device and wherein the control circuitry is arranged such that the at least 50% reduction in output power is effected by reducing the period of conduction of the device during individual cycles of radio frequency oscillation independently of the supply voltage to the device.
- 20 11. A system according to claim 10, wherein the sensing circuit and the power adjustment circuits are operable repeatedly to effect a rapid reduction in the cycle by cycle conduction period of the power device from a peak level to a trough level followed by a less rapid progressive increase in the conduction period until the conduction period again reaches its peak level, the rapid reduction and progressive increase sequence being repeated while simultaneously reducing the supply voltage to said output stage until said peak conduction period level can be reached without the output voltage exceeding said predetermined threshold.
- 25 12. An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, comprising an instrument body, an elongate instrument shaft and, at a distal end of the shaft, an electrode assembly, wherein the electrode assembly comprises
- 30 a single active electrode having an exposed tissue treatment portion, and



a return electrode having a fluid contact surface set back from the treatment portion of the active electrode and spaced from the treatment portion by an insulation member such that when the treatment portion is brought adjacent a tissue surface immersed in the fluid medium the fluid contact surface is normally spaced from the tissue surface and the fluid medium completes a conduction path between the active electrode and the return electrode.

- 5
13. An instrument according to claim 12, wherein the return electrode comprises a conductive sleeve located around the insulation member behind the treatment portion of the active electrode.
- 10
14. An instrument according to claim 12, wherein the treatment portion of the active electrode is located at an extreme distal end of the assembly and the fluid contact surface of the return electrode is spaced proximally from the active electrode treatment portion, and wherein the exposed portion of the active electrode has a length and a width, the length being greater than at least one half of the width.
- 15
15. An instrument according to claim 14, wherein the longitudinal spacing of the active electrode exposed portion and the return electrode fluid contact surface is at least 1mm.
- 20
16. An instrument according to claim 15, wherein the ratio of (i) the longitudinal distance between the distal end of the active electrode exposed portion and the most distal part of the return electrode, to (ii) the shortest longitudinal distance between the active electrode exposed portion and the most distal part of the return electrode, is less than or equal to 2 to 1.
- 25
17. An instrument according to claim 15 or claim 16, wherein the return electrode has a fluid contact surface encircling the insulation member and wherein the ratio of (i) the longitudinal distance between the distal end of the active electrode exposed portion and the distal edge of the fluid contact surface of the return electrode to (ii)
- 30

the circumference of the fluid contact surface in the region of its distal edge is less than or equal to 1.43 : 1.

5 18. An instrument according to claim 12, wherein the instrument shaft comprises a metallic tube as its main structural element, and the return electrode is an integrally formed distal end portion of the tube.

10 19. An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid, comprising an instrument body, an elongate instrument shaft and, on a distal end of the shaft, an electrode assembly, wherein the electrode assembly comprises an exposed active electrode treatment interface and an exposed return electrode fluid interface behind the treatment interface and spaced therefrom by a insulation member, the treatment interface projecting outwardly from the insulation member, wherein of the surface area of the fluid  
15 interface is greater than that of the treatment interface, and wherein the treatment interface extends outwardly from the insulation member by a distance which is greater than or equal to one half of its width in a direction perpendicular to the outward direction.

20 20. An instrument according to claim 19, wherein the shaft defines a longitudinal axis, the treatment interface is a conductive axial projection the axial length of which is greater than one half of its lateral width, the insulation member is a coaxial ceramic sleeve located proximally of the projection, and the fluid interface is a conductive outer sleeve surrounding the insulation member and spaced from the  
25 treatment interface by an axial separation of at least 1mm.

30 21. An instrument according to claim 19, wherein the treatment interface extends outwardly from the insulation member by a greater distance than its width in a direction perpendicular to the outward direction.

22. An instrument according to claim 19, wherein the active electrode treatment interface comprises a conductive active electrode tip member the length of which is the outward direction is at least one half of its width, and wherein the insulation member has an end face adjacent the tip member, which face does not extend laterally beyond said tip member by more than one half of said tip member length.
23. An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, the instrument comprising:
- an instrument shaft, and
  - an electrode assembly at a distal end of the shaft, the electrode assembly having a distal end and including an active electrode and a return electrode, with an exposed portion of the active electrode at the distal end of the electrode assembly and a fluid contact surface of the return electrode positioned proximally of the active electrode exposed portion, further including an insulating member positioned between and electrically insulating the active electrode and the return electrode, wherein the exposed portion of the active electrode has a length and a width, and the length of the active electrode exposed portion is greater than the width of the active electrode exposed portion.
24. An instrument according to claim 23, wherein the exposed portion of the active electrode extends longitudinally from the distal end of the shaft.
25. An instrument according to claim 23, wherein the insulation member comprises a generally cylindrical sleeve and the return electrode is located on the outside of the sleeve longitudinally spaced from the exposed portion of the active electrode by a distance of at least 1mm.
26. An instrument according to claim 25, wherein the insulation member has an annular distal end face defining a shoulder, and the active electrode exposed portion is centrally located with respect to and projects from the insulation member end face, the depth of the shoulder in a direction laterally away from the

active electrode being between  $0.05l$  and  $0.5l$ , where  $l$  is the length of the central active electrode exposed portion.

- 5 27. An instrument according to claim 26, wherein the dimensions and configuration of the active electrode exposed portion, the return electrode fluid contact surface and the insulation member are such that when the electrode assembly is immersed in a conductive fluid medium the ratio of (i) the length of the shortest conduction path through the fluid medium between the return electrode fluid contact surface and that part of the active electrode exposed portion which is furthest from the fluid contact surface, to (ii) the length of the shortest conduction path through the fluid medium between the return electrode fluid contact surface and the active electrode portion is less than or equal to 2 to 1.
- 10
- 15 28. An instrument according to claim 27, wherein the length of the shortest conduction path through the fluid medium between the return electrode fluid contact surface and the active electrode exposed portion is at least 1 mm.
- 20 29. An instrument according to claim 27, wherein the return electrode fluid contact surface is annular and has a length and a diameter, the length of the fluid contact surface being at least as great as its diameter, and wherein the ratio of (i) the shortest conduction path through the fluid medium between the return electrode fluid contact surface and that part of the active electrode exposed portion which is furthest from the fluid contact surface, to (ii) the fluid contact surface diameter is at most 4.5 to 1.
- 25
30. An instrument according to claim 24, wherein the insulation member comprises a generally conic member that tapers towards the distal end of the instrument.
- 30 31. A method of desiccating tissue using a bipolar electrode assembly, the assembly including an active electrode and a return electrode, the active electrode having an exposed treatment portion, and the return electrode having an exposed fluid

contact surface spaced and set back from the exposed treatment portion, the method comprising the steps of:

(a) introducing the electrode assembly into a selected operation site;

(b) surrounding the electrode assembly with a conductive fluid so that the conductive fluid defines an electrical path between the active and return electrodes;

(c) applying sufficient radio frequency output power to the electrode assembly to increase the temperature of the conductive fluid adjacent the active electrode treatment portion without creating a vapour pocket surrounding the treatment portion;

(d) contacting the treatment portion to tissue while maintaining the return electrode fluid contact surface out of contact with the tissue.

32. The method of claim 31, wherein step (d) includes maintaining a part of the exposed treatment portion of the active electrode out of contact with the tissue.

33. The method of claim 32, wherein step (d) includes the further step of:  
(e) moving the active electrode across a surface of the tissue.

34. The method of claim 33, wherein step (e) includes moving the electrode across the tissue surface in a side-to-side motion.

35. The method of claim 31, wherein step (c) includes maintaining the temperature of the conductive fluid adjacent to the active electrode treatment portion substantially at the boiling point of the conductive fluid.

36. The method of claim 31, wherein the conductive fluid comprises a saline solution.

37. The method of claim 31, wherein the conductive fluid comprises a compound sodium lactate solution.

38. A method of vaporising tissue using a bipolar electrode assembly, the bipolar electrode assembly including an active electrode and a return electrode, the active electrode having an exposed treatment portion, the method comprising the steps of:

- 5 (a) introducing the electrode assembly into a selected operation site;  
(b) surrounding the electrode assembly with a conductive fluid;  
(c) applying sufficient radio frequency output power to the electrode assembly to vaporise the conductive fluid adjacent the active electrode treatment portion to create a vapour pocket surrounding the treatment portion;

10 (d) positioning the treatment portion of the active electrode adjacent the tissue with the vapour pocket in contact with the tissue while maintaining the return electrode out of contact with the tissue.

39. The method of claim 38, wherein step (d) includes the further step of:

- 15 (e) moving the active electrode treatment portion over a surface of the tissue.

40. The method of claim 39, wherein step (e) includes moving the electrode over the tissue surface in a side-to-side motion.

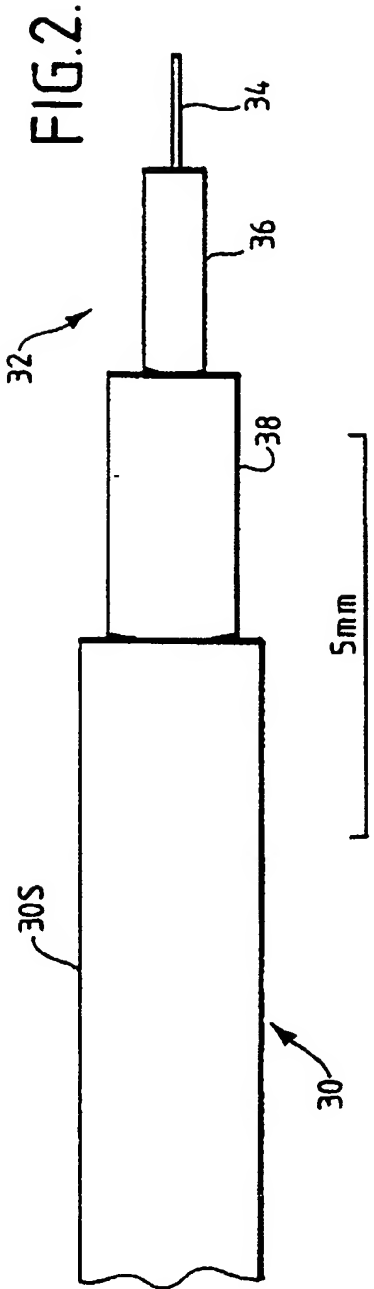
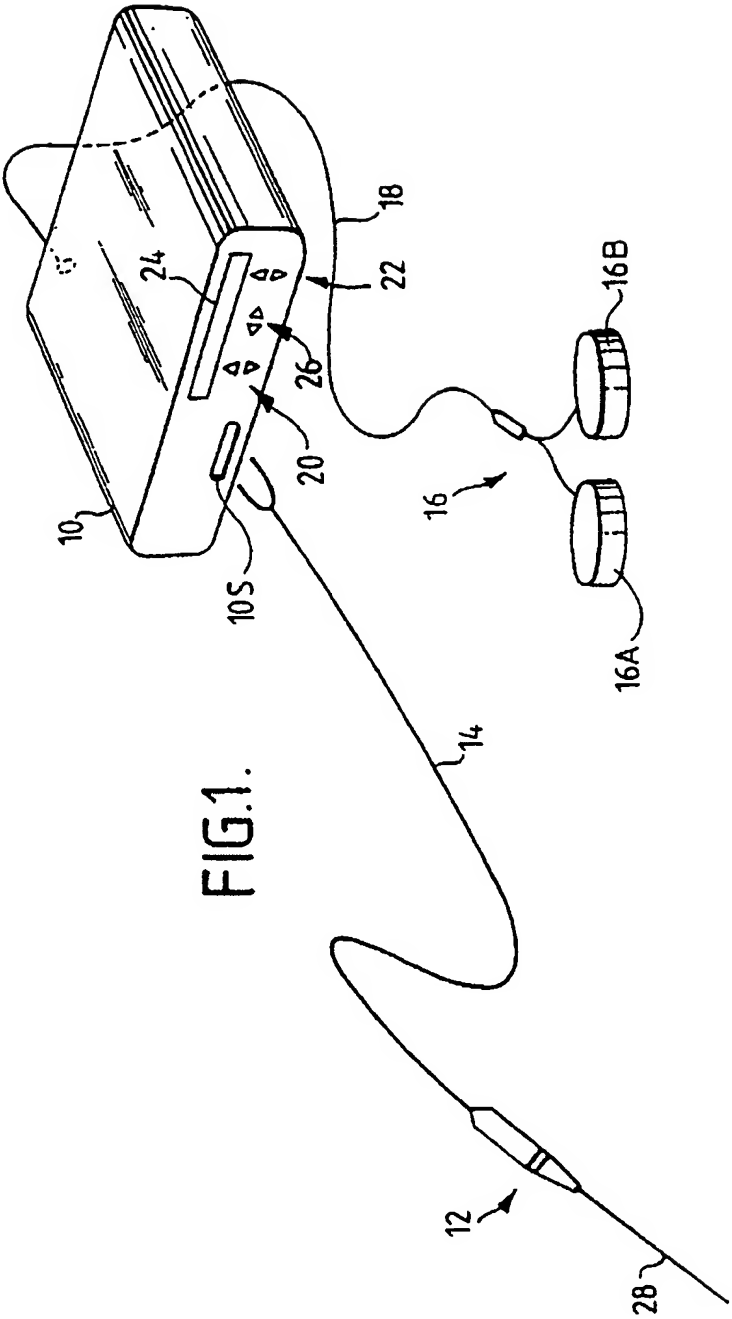
20 41. The method of claim 39, wherein step (e) includes moving the active electrode over the surface of the tissue to contour the tissue.

25 42. The method of claim 38, wherein the conductive fluid comprises a saline solution.

43. The method of claim 38, wherein the conductive fluid comprises a compound sodium lactate solution.

30 44. The method of claim 38, wherein the treatment portion of the active electrode is a distal end portion and the exposed fluid contact surface of the return electrode is proximally spaced from the treatment portion, and wherein step (a) includes

positioning a part of the exposed treatment portion adjacent and from time to time in contact with the tissue.





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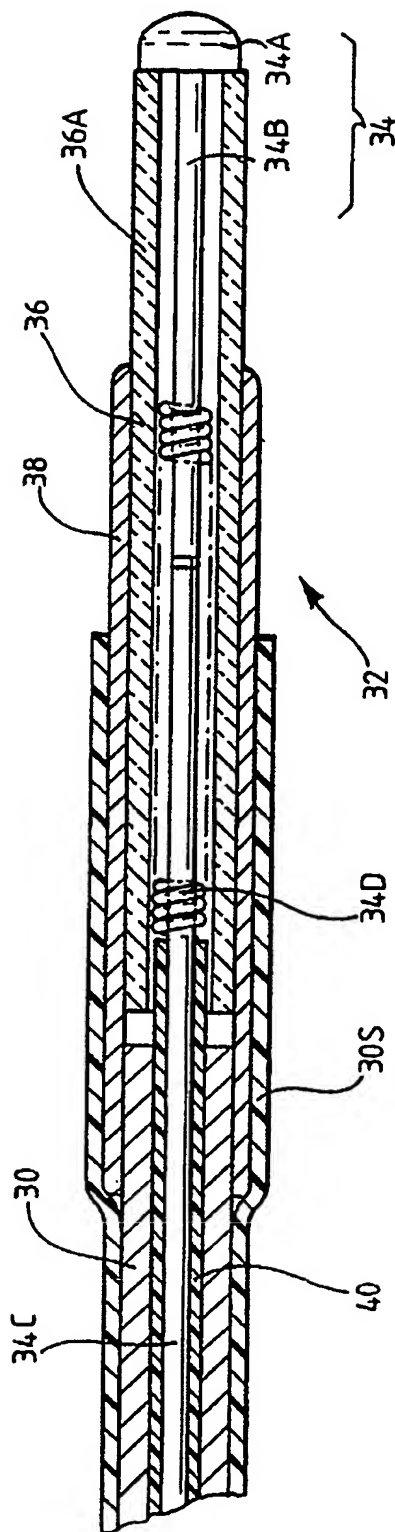
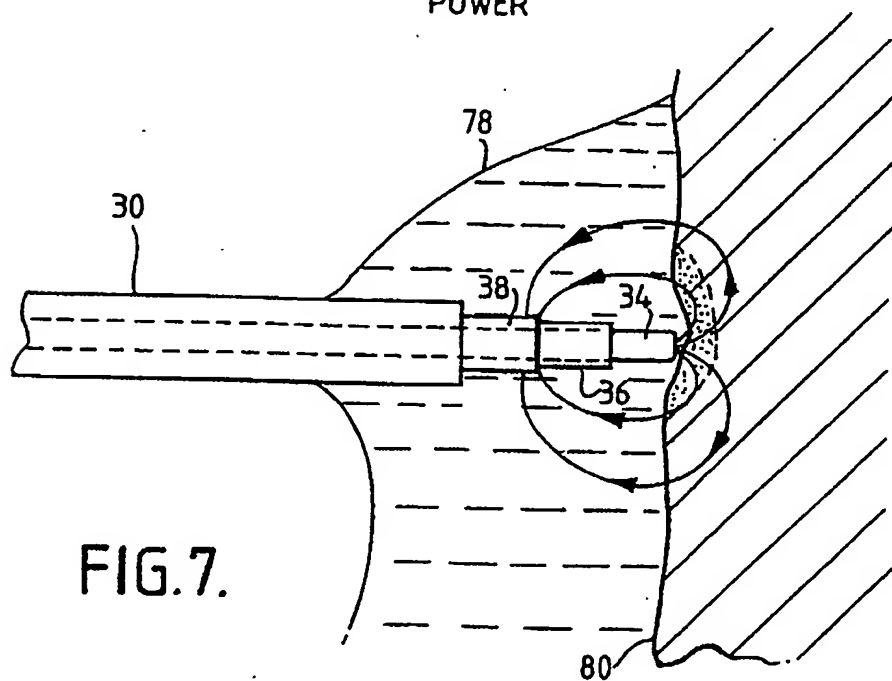
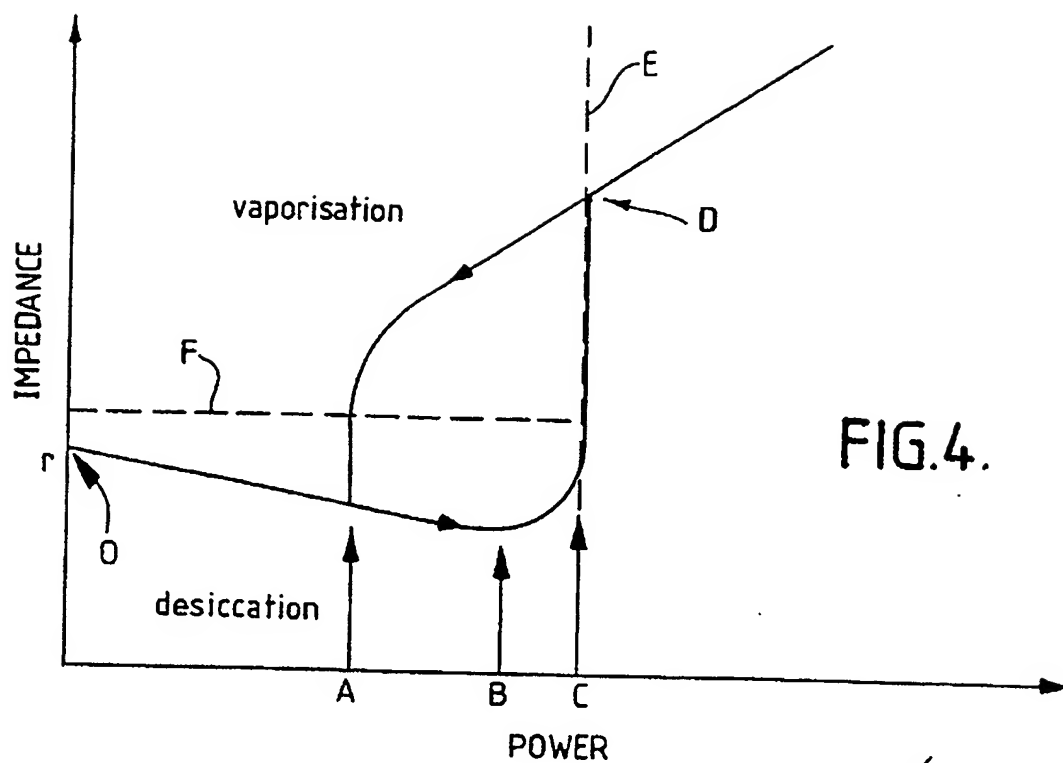


FIG. 3.

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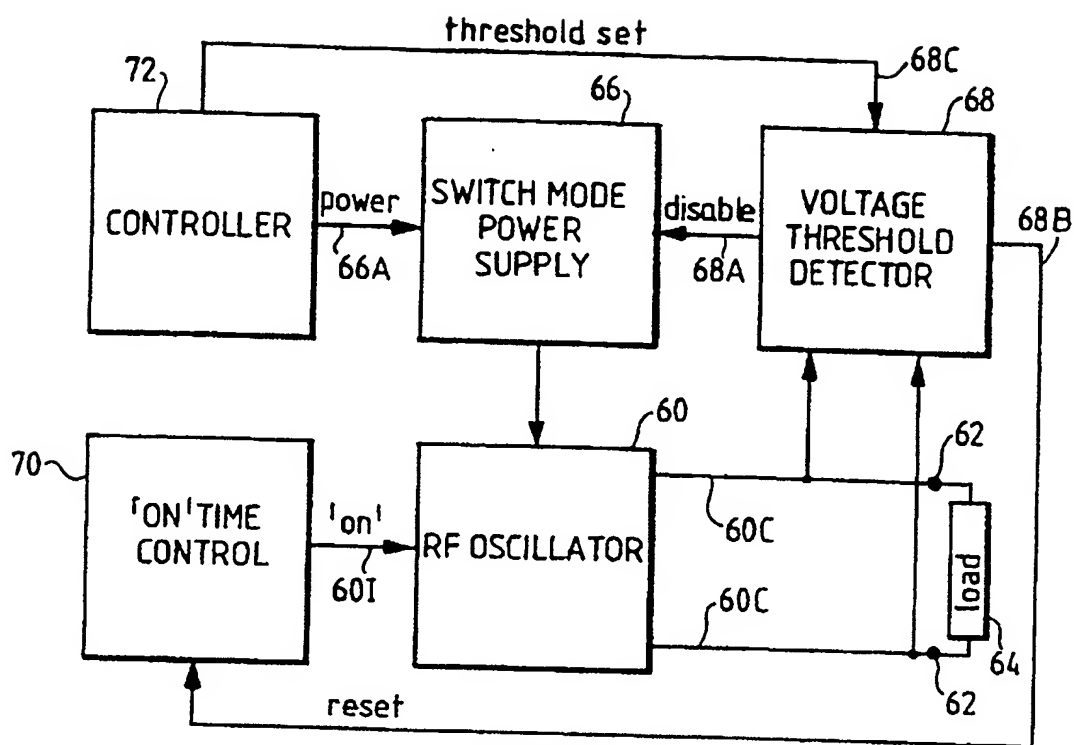


FIG. 5.

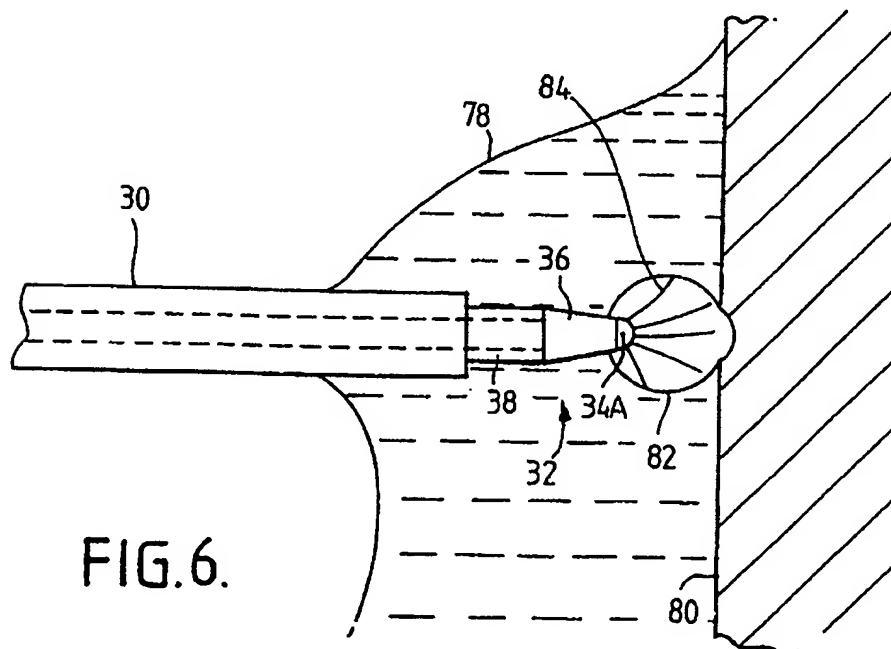
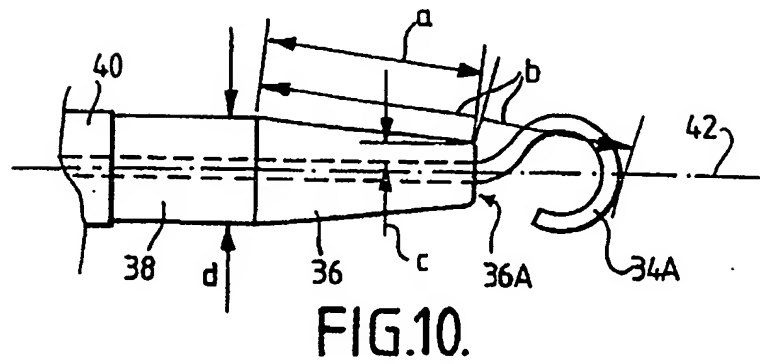
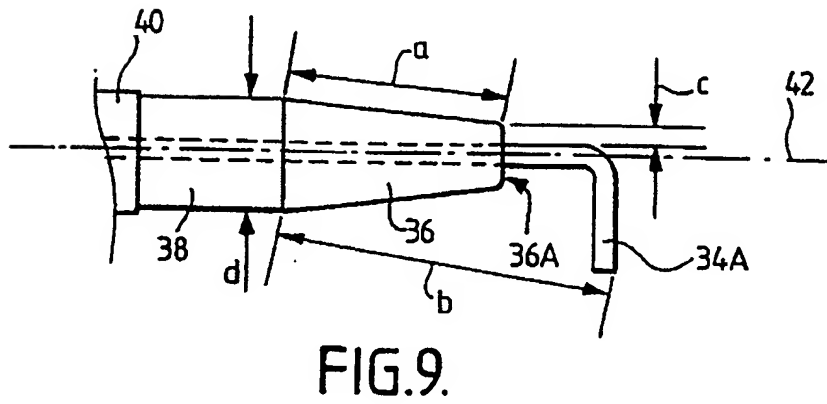
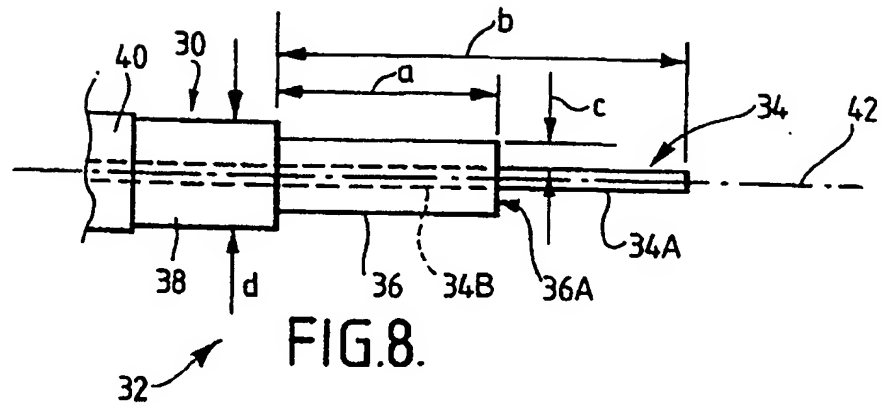


FIG. 6.

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# INTERNATIONAL SEARCH REPORT

Int. Application No  
PCT/GB 96/01473

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,93 19681 (VALLEYLAB) 14 October 1993 see page 4, line 14 - line 18 ---	1,12,19
A	US,A,5 261 906 (PENNINO) 16 November 1993 see abstract; figures 1-9 ---	1
A	US,A,4 706 667 (ROOS) 17 November 1987 cited in the application see abstract -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

8 October 1996

Date of mailing of the international search report

14. 10. 96

Name and mailing address of the ISA

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Authorized officer

Papone, F

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB96/01473

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 31-44  
because they relate to subject matter not required to be searched by this Authority, namely:  
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

(Information on patent family members)

International Application No

PCT/GB 96/01473

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9319681	14-10-93	US-A- 5281216 AU-A- 3430693 CA-A- 2130554 DE-U- 9390075 EP-A- 0633749 FI-A- 944522 JP-T- 7501474 NO-A- 943627	25-01-94 08-11-93 14-10-93 03-11-94 18-01-95 29-09-94 16-02-95 29-09-94
US-A-5261906	16-11-93	NONE	
US-A-4706667	17-11-87	DE-A- 3423356	02-01-86